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What Should Clinical Laboratories Expect in 2017?

This is the first in a two-part series.

Within hours of taking office, President Donald Trump began the process of repealing and replacing the Patient Protection and Affordable Care Act of 2010 and healthcare provisions of the Healthcare and Education Reconciliation Act of 2010 (collectively, the ACA). The President issued a broad executive order instructing the U.S. Department of Health and Human Services (HHS) to ease regulatory requirements and penalties under the ACA for insurers, individuals and other healthcare stakeholders, to the extent permitted by law. The clinical laboratory community should prepare for significant disruptions in the healthcare marketplace even as it continues to grapple with major policy shifts set into motion in the final years of the Obama administration.

Clinical labs faced a number of significant changes during President Barack Obama's second term. Implementation of the MolDx program, followed by enactment of the Protecting Access to Medicare Act of 2014, effectively completely revamped (and in certain cases substantially reduced) Medicare payments to laboratories. In addition, the HHS Office of Inspector General repeatedly exercised its enforcement authority with a focus on the practices of labs trying to compete in an ultracompetitive world — issuing a Special Fraud Alert limiting many specimen collection and bioregistry fees, and aggressively pursuing labs for alleged Anti-Kickback Statute, Stark Law and inducement-of-beneficiary violations. Privacy laws and clinical research laws also placed restrictions and regulatory requirements on entities collecting, using and disclosing genetic and genomic data. And implementation of the ACA created a network of integrated exchanges and public and private accountable care organizations that left many laboratories out of network and, in some cases, out in the cold in terms of coverage and reimbursement.

Even with all of these changes and challenges, clinical lab tests continue to be an essential part of medical encounters, guiding 70 percent of medical decisions and providing clinicians with the critical information they need to diagnose, treat and prevent myriad illnesses and ailments across populations.[1] Newer esoteric

[1] See American Clinical Laboratory Association, *Importance of Clinical Lab Testing Highlighted During Medical Lab Professionals Week* (Apr. 17, 2014), available at http://www.acla.com/importance-of-clinical-lab-testing-highlighted-during-medical-lab-professionals-week/.

laboratories are developing novel genomic, proteomic, companion diagnostic and other complex tests using technological advances like next generation sequencing and algorithmic analysis that have the potential to add considerable value to medical treatment. While law, policy and reimbursement have lagged behind scientific advancement, there is continued innovation and investment in the lab industry.

So, what should we expect in 2017?

The ACA

President Trump's picks to lead both HHS and the Centers for Medicare & Medicaid Services (CMS) signal that he plans to make good on his promise to repeal and replace the ACA and shake up Medicaid. For providers of clinical lab testing services, there is a lot at stake regarding coverage of laboratory services in the GOP-backed ACA repeal-and-replace proposals. While President Trump himself has not articulated his policy proposals in this regard, other proposals may provide some insight.

For example, GOP-backed replacements for the ACA generally take a market-driven approach to healthcare, shifting costs from payors to the consumer and cutting back on covered services. Most of the replacement plans would eliminate the essential health benefits (EHB) mandate enacted through the ACA and implemented through HHS regulations. That is true of Speaker Paul Ryan's A Better Way plan, HHS Secretary nominee Tom Price's Empowering Patients First plan and the Republican Study Committee's American Health Care Reform Act. The ACA's EHB package guarantees coverage of laboratory services (among other categories of benefits) in certain health insurance plans.

All of these GOP replacement plans would repeal the preventive health services requirement, which requires all non-grandfathered private health insurance plans to provide coverage for certain recommended laboratory services (including certain women's health preventive services) at no cost. These plans also seek to move consumers toward high-deductible health plans supported by tax-free health savings accounts (HSAs) with the aim of keeping premiums low. However, increased cost-sharing would likely decrease discretionary healthcare spending and negative implications for clinical labs, especially those offering boutique tests as opposed to more routine care. Medicare Part B does not currently require copayments by beneficiaries, although policymakers occasionally question this exemption. Medicaid and private commercial payors typically do require such copayments, and the increased privatization and cost-shifting to consumers may adversely affect clinical labs by pricing their tests out of the reach of many consumers.

Medicaid Expansion

Repealing and replacing the ACA would also have significant effects on the ACA Medicaid expansion, which has been enacted in 31 states and the District of Columbia and has realized an overall enrollment growth of approximately 26.5 percent since the first open enrollment period in October 2013. More than 2.5 million people in GOP-represented states have enrolled in Medicaid through expanded eligibility.[2] Seema Verma, the President's nominee to head CMS, consulted on Medicaid expansion in Indiana and other GOP states. The Healthy Indiana Plan 2.0 that Verma designed parallels the "consumer-driven" plans of Speaker Ryan and Rep. Price (R-GA) in a number of ways, particularly by centering on high-deductible health plans and HSAs. Healthy Indiana Plan 2.0 mandates coverage of EHBs per the ACA, but it is possible that mandates like this will be weakened though regulatory action or eliminated through legislative action.

[2] See https://www.medicaid.gov/medicaid/program-information/downloads/cms-64-enrollment-report-oct-dec-2015.pdf.

A full-scale repeal of the Medicaid expansion could be politically difficult due to the number of states that have already expanded their Medicaid programs under the ACA. Even if the Medicaid expansions stay intact, however, Republicans may seek to roll back covered services for the expansion population consistent with other ACA repeal-and-replace legislative policies. It is also possible that the Congress will lower the enhanced federal match rate for states for the expansion population. Additional Medicaid reform proposals are on the table, including proposals to reduce the scope of benefits under the program or to restructure it into a block grant program or capitation model.

Next

Clinical laboratories should closely watch legislative and regulatory actions in these key areas. Significant opportunities will exist for laboratories to affect policy as it develops. We will be closely monitoring developments and would be happy to address your questions or concerns.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

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Sidley Government Strategies Practice

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